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10/599,729	10/06/2006	Jong Soo Woo	Q97584	3327

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EXAMINER	
FISHER, ABIGAIL L	
ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/599,729	WOO ET AL.	
	Examiner	Art Unit	
	ABIGAIL FISHER	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-11 and 13-17* is/are pending in the application.

4a) Of the above claim(s) *16 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7, 9-11 and 13-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Amendments/Remarks filed on June 30 2010 is acknowledged. Claims 8 and 12 were/stand cancelled. Claims 1, 9-10 and 13 were amended. Claims 1-7, 9-11 and 13-17 are pending. Claims 16-17 are withdrawn thus, claims **1-7, 9-11 and 13-15** are under examination.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Restrictions

Applicant's confirmation of the election without traverse of Group I in the reply filed on June 30 2010 is acknowledged.

Claims 16-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 30 2010.

Specification

Acknowledgement is made of Applicants' amendments to the specification filed June 30 2010.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Modified Rejection Based on amendments in the reply filed on June 30 2010

Claims 1, 3-7, 9-11 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gutierrez-Rocca et al. (US Patent No. 6524615, cited in the Office action mailed on 3/30/10) in view of Baichwal et al. (US Patent No. 5135757, cited in the Office action mailed on 3/30/10) as evidenced by Mosquera et al. (Int. J. Pharmaceutics, 1996, cited in the Office action mailed on 3/30/10).

Applicant Claims

The instant application claims a sustained release formulation comprising a HMG-CoA reductase inhibitor, a solubilizing agent, a stabilizing agent, a mixture of sodium alginate and xanthan gum as a carrier and a mixture of propylene glycol ester alginate and hydroxypropyl methyl cellulose as a gel hydration accelerator.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Gutierrez-Rocca et al. claim a sustained or prolonged release pharmaceutical unit dosage form comprising a hard shell capsule and a formulation comprising (1) water insoluble medicament such as atorvastatin, simvastatin, lovastatin (all HMG-CoA reductase inhibitors); (2) a high melting fatty acid ester: (3) low viscosity oil (wherein 2 and 3 read on carrier); (4) a cellulosic polymer such as methocel E series and K series which read on gel hydration accelerator; (4) a non-ionic surfactant such as poloxamers and d-2-tocopheryl polyethylene glycol 1000 succinate (which read on solubilizer) (claim 1). It is taught that pharmaceutically acceptable expcipients can be added such as stabilizers/antioxidants like butylated hydroxyl toluene or ascorbic acid (column 6, lines 6-8). It is taught that that the incorporation of lubricants like waxes and high melting

glyceride in tablet matrices have been a popular method to prolong drug release (column 1, lines 64-65). Suitable carriers for the invention include high melting fatty acid ester esters, low viscosity oils and cellulosic polymers (column 3, lines 52-64). An exemplified formulation comprises lovastatin, compritol 888 and olive oil (3.8 weight part), methocel K100M (0.15 weight part), polysorbate 80 (0.05 weight part).

Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)

While Gutierrez-Rocca et al. teach that the composition can comprise excipients such as stabilizers/antioxidants like butylated hydroxyl toluene or ascorbic acid, Gutierrez-Rocca et al. do not exemplify formulations comprising these stabilizers.

While Gutierrez-Rocca et al. claim the statin can be simvastatin, Gutierrez-Rocca et al. do not exemplify formulations comprising simvastatin.

While Gutierrez-Rocca et al. claim the surfactant can be a poloxamer or d-2-tocopheryl polyethylene glycol 100 succinate, Gutierrez-Rocca et al. do not exemplify these surfactants.

While Gutierrez-Rocca et al. teach that the sustained release formulation comprises cellulosic polymers such as methocel K100M, Gutierrez-Rocca et al. do not teach the inclusion of the hydrophilic polymers such as sodium alginate, locust bean gum, xanthan gum and propylene glycol ester alginate. However these deficiencies are cured by Baichwal et al.

Baichwal et al. is directed to compressible sustained release solid dosage forms. The invention provides a slow release granulation for use as a directly compressible

pharmaceutical excipient. It comprises a heteropolysaccharide or a gum having similar properties and a polysaccharide material capable of crosslinking. The ratio of heteropolysaccharide to the polysaccharide material being from about 1:1 to about 4:1 (column 4, lines 40-47). Heteropolysaccharides taught include xanthan gum (column 5-6, lines 55-68 and 1-4). Crosslinking polysaccharides taught are preferably locust bean gum due to its higher ratio of mannose to galactose (column 6, lines 5-19). It is taught that other hydrophilic material can be added such as alginates, hydroxypropymethyl cellulose and the like (column 6, lines 20-28). It is taught that certain other polysaccharide gums including alginic acid derivates are believed to act synergistically with xanthan gum to produce matrices having high gel strength. The combination of xanthan gum with locust bean with or without the other polysaccharides gums is especially preferred. Known combinations with are known to produce synergistic results include propylene glycol alginate and sodium carboxymethylcellulose (column 6, lines 49-68). Specific compositions taught are xanthan gum, locust bean gum, propylene glycol alginate (example 23 and 24), xanthan gum, locust bean gum and hydroxypropylmethyl cellulose (Examples 25 and 26) and xanthan gum, locust bean gum and sodium alginate (example 27). The ratios of xanthan gum to locust bean gum to other hydrophilic material is 1:1:2.

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Gutierrez-Rocca et al. and Baichwal et al.

and utilize a combination of heteropolysaccharides and polysaccharides in the sustained release composition of Gutierrez-Rocca et al. One of ordinary skill in the art would have been motivated to utilize a combination of heteropolysaccharides and polysaccharides as Baichwal et al. teach that combination act synergistically to provide matrices having high gel strength. Specific combinations taught include xanthan gum, locust bean gum, propylene glycol alginate; xanthan gum, locust bean gum and hydroxypropylmethyl cellulose; and xanthan gum, locust bean gum and sodium alginate. Therefore, it would have been obvious to one of ordinary skill in the art to manipulate the hydrophilic polymers utilized in order to obtain a synergistic combination for increasing gel strength as taught by Baichwal et al.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Gutierrez-Rocca et al. and Baichwal et al. and utilize a stabilizer such as ascorbic acid or butylated hydroxyl toluene in the sustained release composition. One of ordinary skill in the art would have been motivated to utilize a stabilizer as they are excipients taught by Gutierrez-Rocca et al. that can be included. Therefore, one of ordinary skill in the art would have been motivated to add them in order to stabilize the sustained release formulations as taught by Gutierrez-Rocca et al.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Gutierrez-Rocca et al. and Baichwal et al. and utilize simvastatin as the medicament. One of ordinary skill in the art would have been motivated to utilize simvastatin as it is a specifically claimed medicament. One of

ordinary skill in the art would have been motivated to replace the exemplified lovastatin with simvastatin as both are taught by Gutierrez-Rocca et al. as functional equivalents. Further more, the selection of a specific drug is considered prima facie obvious depending on the desired condition/symptoms to be treated.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Gutierrez-Rocca et al. and Baichwal et al. and utilize a poloxamer or d-2-tocopheryl polyethylene glycol 100 succinate as the surfactant. One of ordinary skill in the art would have been motivated to utilize these surfactants are they are ones specifically claimed. One of ordinary skill in the art would have been motivated to replace the exemplified polysorbate 80 with a poloxamer or d-2-tocopheryl polyethylene glycol 100 succinate as all are taught by Gutierrez-Rocca et al. as functional equivalents.

Regarding the claimed amount of the hydrophilic polymers is 1 part xanthan gum, 1 part locust bean gum and 2 parts of other hydrophilic material. These amounts read on the amounts claimed. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. It would have been obvious to one of ordinary skill in the art to manipulate the amount of polysaccharides in order to determine amounts which produce synergistic results as

taught by Baichwal et al. It would have been obvious to one of ordinary skill in the art at the time of the invention to engage in routine experimentation to determine optimal or workable ranges that produce expected results. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F. 2d 454, 105 USPQ 233 (CCPA 1955).

Regarding claim 14, as evidenced by Mosquera et al. Methocel K100M has a viscosity of 100,000 CP (page 147).

Regarding claim 15, the high melting glycerides read on lubricant.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gutierrez-Rocca et al. in view of Baichwal et al. as evidenced by Mosquera et al. and in further view of Serajuddin et al. (US Patent No. 5433951, cited in the Office action mailed on 3/30/10).

Applicant Claims

The instant application claims the solubilizing agent is 0.05 to 20 weight part; the stabilizing agent is 0.01 to 0.1 weight part; the sustained release composite carrier is 3

to 30 weight part; and the gel hydration accelerator is 0.1 to 5 weight part based on 1 weight part of the HMG- CoA reductase inhibitor.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Gutierrez-Rocca et al. are set forth above. Specifically, Gutierrez-Rocca et al. exemplify a formulation comprises lovastatin, compritol 888 and olive oil (3.8 weight part), methocel K100M (0.15 weight part), polysorbate 80 (0.05 weight part). Other non-ionic surfactant taught include poloxamers and d-2-tocopheryl polyethylene glycol 1000 succinate. It is taught that pharmaceutically acceptable excipients can be added such as stabilizers/antioxidants like butylated hydroxyl toluene or ascorbic acid (column 6, lines 6-8).

Ascertainment of the Difference Between the Scope of the Prior Art and the Claims
(MPEP §2141.012)

While Gutierrez-Rocca et al. teach stabilizers can be added, Gutierrez-Rocca et al. do not teach amounts that are suitable. However, this deficiency is cured by Serajuddin et al.

Serajuddin et al. is directed to sustained release formulations. It is taught that antioxidants for fatty acid glycerides such as ascorbic acid or butylated hydroxy toluene can be present in an amount within the range from about 0.005 to about 2%, preferably from about 0.01 to about 1% (column 3, lines 51-27).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Gutierrez-Rocca et al. and Serajuddin et al. and utilize the antioxidants in an amount from about 0.005 to about 2%. One of ordinary skill in the art would have been ;motivated to utilize this amount as the antioxidants are taught by Gutierrez-Rocca et al. as being suitable to add and the compositions comprise fatty acid glycerides and Serajuddin et al. teach this is an amount suitable to stabilize fatty acid glycerides. Therefore, one of ordinary skill in the art would have been motivated to utilize the antioxidants in this amount based on the teachings of Serajuddin et al.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1, 3-4, 7, 9-11 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Louie-Helm et al. (USPGPUB No. 20030091630, cited in the Office action mailed on 3/30/10) in view of Baichwal et al.

Applicant Claims

The instant application claims a sustained release formulation comprising a HMG-CoA reductase inhibitor, a solubilizing agent, a stabilizing agent, a mixture of

sodium alginate and xanthan gum as a carrier and a mixture of propylene glycol ester alginate and hydroxypropyl methyl cellulose as a gel hydration accelerator.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Louie-Helm et al. is directed to a formulation of an erodible gastric retentive oral dosage form. The invention provides a controlled release dosage form (paragraph 006). Sellable, bioerodible polymers which detemrin the rate at which the polymer matrix erodes include cellulosic polymers such as hydroxypropyl methylcellulose with viscosity in the rage of about 50 to 110,000 (praragrph 0059, 0063 and 0082) and polysaccharide gums such as xanthan gum (paragraph 0079 and 0084) as well as natural polymer s such as alginates (paragraph 0086). It is taught that the water-swellable polymers can be used individually or in combination. Examples of combination include a cellulosic polymer combined with a gum such as hydroxypropylcellulose with xanthan gum (paragraph 0090). The amount of polymer relative to the drug can vary depending the polymer used, molecular weight and excipients that may be present (paragraph 0093). Ranges of drug to polymer claimed is from about 1:500 to about 85:15 (claim 13). Drugs taught include HMG-CoA reductase inhibitors such as simvastatin and lovastatin (paragraph 0110 and claim 23). Tablets prepared for oral administration will generally contain other materials such as binders, lubricants, stabilizers, surfactants (solubility enhancers). Stabilizers are used to inhibit or retard drug decomposition reactions (paragraph 0129).

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

While Louie-Helm et al. teach solubilizers and stabilizers can be added, Louie-Helm et al. do not exemplify formulations comprising these ingredients.

While, Louie-Helm et al. teach that the matrix can be made from cellulosic polymers, gums and alginates and combinations thereof, Louie-Helm et al. do not exemplify formulations comprising sodium alginate, xanthan gum and locust bean gum or hydroxypropyl methylcellulose, propylene glycol ester alginate and the other polymers. However, this deficiency is cured by Baichwal et al.

Baichwal et al. is directed to compressible sustained release solid dosage forms. The invention provides a slow release granulation for use as a directly compressible pharmaceutical excipient. It comprises a heteropolysaccharide or a gum having similar properties and a polysaccharide material capable of crosslinking. The ratio of heteropolysaccharide to the polysaccharide material being from about 1:1 to about 4:1 (column 4, lines 40-47). Heteropolysaccharides taught include xanthan gum (column 5-6, lines 55-68 and 1-4). Crosslinking polysaccharides taught is preferably locust bean gum due to its higher ratio of mannose to galactose (column 6, lines 5-19). It is taught that other hydrophilic material can be added such as alginates, hydroxypropymethyl cellulose and the like (column 6, lines 20-28). It is taught that certain other polysaccharide gums including alginic acid derivates are believed to act synergistically with xanthan gum to produce matrices having high gel strength. The combination of xanthan gum with locust bean with or without the other polysaccharides gums is especially preferred. Known combinations with are known to produce synergistic

results include propylene glycol alginate and sodium carboxymethylcellulose (column 6, lines 49-68). Specific compositions taught are xanthan gum, locust bean gum, propylene glycol alginate (example 23 and 24), xanthan gum, locust bean gum and hydroxypropylmethyl cellulose (Examples 25 and 26) and xanthan gum, locust bean gum and sodium alginate (example 27). The ratios of xanthan gum to locust bean gum to other hydrophilic material is 1:1:2.

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Louie-Helm et al. and Baichwal et al. and utilize a combination of heteropolysaccharides and polysaccharides in the sustained release composition of Louie-Helm et al. One of ordinary skill in the art would have been motivated to utilize a combination of heteropolysaccharides and polysaccharides as Louie-Helm teach these polymers can be utilized and suggest combinations of polymers like xanthan gum and cellulosic polymers and Baichwal et al. teach that combinations act synergistically to provide matrices having high gel strength. Specific combinations taught include xanthan gum, locust bean gum, propylene glycol alginate; xanthan gum, locust bean gum and hydroxypropylmethyl cellulose; and xanthan gum, locust bean gum and sodium alginate. Therefore, it would have been obvious to one of ordinary skill in the art to manipulate the hydrophilic polymers utilized in order to obtain a synergistic combination for increasing gel strength as taught by Baichwal et al.

Regarding the claimed amount of the hydrophilic polymers is 1 part xanthan gum, 1 part locust bean gum and 2 parts of other hydrophilic material. These amounts read on the amounts claimed. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. It would have been obvious to one of ordinary skill in the art to manipulate the amount of polysaccharides in order to determine amounts which produce synergistic results as taught by Baichwal et al. It would have been obvious to one of ordinary skill in the art at the time of the invention to engage in routine experimentation to determine optimal or workable ranges that produce expected results. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F. 2d 454, 105 USPQ 233 (CCPA 1955).

Regarding claim 14, the viscosity of the cellulosic polymers taught by Louie-helm et al. overlap those instantly claimed. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. **See MPEP 2144.05 [R-5]**

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the

instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1, 3-7, 9-11 and 13-15 are provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 10650931 (Woo et al., PGPUB No. 20040081693) which has a common inventor with the instant application in view of Gutierrez-Rocca et al. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if published or patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future publication or patenting of the conflicting application.

This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131. This rejection might also be overcome by showing that the copending application is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Applicant Claims

The instant application claims a sustained release formulation comprising a HMG-CoA reductase inhibitor, a solubilizing agent, a stabilizing agent, a mixture of sodium alginate and xanthan gum as a carrier and a mixture of propylene glycol ester alginate and hydroxypropyl methyl cellulose as a gel hydration accelerator.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Woo et al. claim a sustained release composition comprising a mixture of sodium alginate and xanthan gum, hydroxypropylmethylcellulose and propylene glycol alginate (claim 2). The ratio of drug: carrier:accelerator is 1:3-30:0.1-15 (claim 3). The weight ratio of sodium alginate and xanthan gum is 1:0.1-10 (claim 4). The composition further comprises locust bean gum (claim 5). Ratio of sodium alginate:xanthan gum:locust bean gum is 1:0.2-10:0.1-5 (claim 6). Weight ratio of hydroxy propylmethylcellulose and propylene glycol alginate is in the range of 1:0.05-20 (claim7). Drugs include drugs for hyperlimidemia (claim 8) such as lovastatin (claim 9). Other drugs for hyperlipidemia taught include simvastatin (paragraph 0022). It is taught that the composition may additionally include stabilizers, lubricants, wetting agents, flavoring agent, emulsifiers and the like (paragraph 0030).

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

While Woo et al. teach that the composition can comprise simvastatin, stabilizers, emulsifiers and other excipients like flavoring agents, Woo et al. do not exemplify these combinations.

While Woo et al. teach stabilizers and emulsifiers can be added, Woo et al. do not specify specific examples of these components. However, this deficiency is cured by Gutierrez-Rocca et al.

Gutierrez-Rocca et al. claim a sustained or prolonged release pharmaceutical unit dosage form comprising a hard shell capsule and a formulation comprising (1) water insoluble medicament such as atorvastatin, simvastatin, lovastatin (all HMG-CoA reductase inhibitors); (2) a high melting fatty acid ester: (3) low viscosity oil (wherein 2 and 3 read on carrier); (4) a cellulosic polymer such as methocel E series and K series which read on gel hydration accelerator; (4) a non-ionic surfactant such as poloxamers and d-2-tocopheryl polyethylene glycol 1000 succinate (which read on solubilizer) (claim 1). It is taught that pharmaceutically acceptable excipients can be added such as stabilizers/antioxidants like butylated hydroxyl toluene or ascorbic acid (column 6, lines 6-8).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Woo et al. and Gutierrez-Rocca et al. and utilize stabilizer and solubilizer in the sustained release formulation of Woo et al. One of ordinary skill in the art would have been motivated to utilize these components as Woo et al. suggest that they can be utilized in the formulations. Therefore, it would have

been obvious to one of ordinary skill to add these components in order to aid in solubilization and stabilization as taught by Woo et al.

Regarding the specifically, claimed stabilizers and solubilizers, Gutierrez-Rocca et al. teach stabilizers/antioxidants like butylated hydroxyl toluene or ascorbic acid and surfactant such as poloxamers and d-2-tocopheryl polyethylene glycol 1000 succinate which are taught as being suitable for use with statins. Therefore, it would have been obvious to choose these specific stabilizers and surfactants as they are known to be utilize in sustained release formulations wherein the active agent is a statin.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments/Declaration under Rule 1.132

Applicants argue that (1) the instantly claimed composition is not prepared by simply mixing but by a two-step process. It is argued that Gutierrez-Rocca fails to disclose a solid dispersant which is prepared before adding a sustained release composite carrier and gel hydration accelerator thereto. It is argued that (2) to demonstrate the remarkable effects of the subjection invention, the declaration shows markedly improved solubility, bioavailability and stability. Applicants argue that (3) that Woo is silent to the feature of the instantly claimed solid dispersant.

Applicants' arguments filed June 30 2010 have been fully considered but they are not persuasive.

The declaration under 37 CFR 1.132 filed June 30 2010 is insufficient to overcome the rejection of claims 1-7, 9-11 and 13-15 as set forth in the last Office action because: the declaration establishes the importance of the method of making the product, however the instant claims are directed to a composition. Therefore, the declaration is not related to the composition as claimed.

Applicants argue the importance of the method of making the product and refer to the declaration to show that the method of making produces a product which has improved solubility, bioavailability and stability. However, this is not persuasive as the instant claims are directed to a composition comprising the specifically disclosed ingredients. Since a product comprising these components would have been obvious based on the cited prior art, the prior art meets the composition components and therefore the product is obvious.

Regarding the provisional rejection over Woo, first the Woo reference is utilized for its filing date which is before the publication date of the instant priority reference. Furthermore, Woo teaches the a composition comprising the instantly claimed components. Therefore, the product is still obvious based on the teachings of Woo.

Therefore, the rejection is maintained since applicant has not provided any persuasive arguments to overcome the rejection.

Double Patenting/Terminal Disclaimer

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 1-15 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5-6, 8 and 10 of copending Application No. 10650931 (now US Patent No. 7704526) in view of Gutierrez-Rocca et al. is **withdrawn** in light of the filing of the terminal disclaimer on August 2 2010.

The terminal disclaimer filed on August 2 2010 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent No. 7704526 (Application No. 10650931) has been reviewed and is accepted. The terminal disclaimer has been recorded.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher
Examiner
Art Unit 1616

AF

/Mina Haghighatian/
Primary Examiner, Art Unit 1616